

# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.usplo.gov

Re-Mail

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,306	09/20/2001	Michel Auguet	427-047	840.7
7590 12/07/2004			EXAMINER	
MUSERLIAN 475 PARK AVI	I, LUCAS AND MER ENUE SOUTH	MELLER, MICHAEL V		
NEW YORK, NY 10016			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 12/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.





## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCI United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandra, Viguna 22313-1450

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/937,306	09/20/2001	Michel Auguet	427-047	8402	
7590 11/19/2004			EXAMINER		
Bierman Muserlian and Lucas			MELLER, MICHAEL V		
600 Third Avenue New York, NY 10016			ART UNIT	PAPER NUMBER	
		•	1654		
			DATE MAILED: 11/19/2004		

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)						
and Add D	09/937,306	AUGUET ET AL.						
Office Action Summary	Examiner	Art Unit						
	Michael V. Meller	1654						
The MAILING DATE of this communication appears on the cover sheet with the correspondence address eriod for Reply								
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 37 CFR 1.138(e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).								
atus								
1) Responsive to communication(s) filed on 19 Oc	tober 2004.							
·_ · ·	action is non-final.							
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
sposition of Claims								
	Claim(s) 1.4 and 8-12 is/are pending in the application.							
5) Claim(s) is/are allowed.	4a) Of the above claim(s) is/are withdrawn from consideration.							
6) Claim(s) 1.4 and 8-12 is/are rejected.								
7) Claim(s) is/are objected to.								
B) Claim(s) are subject to restriction and/or	plantian requirement							
b)[] Claim(s) are subject to restriction and/or	election requirement.							
plication Papers		•						
9) The specification is objected to by the Examiner								
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.								
• •	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
ority under 35 U.S.C. § 119		·						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>								
nchment(s)								
Notice of References Cited (PTO-892)	4) Interview Summary (	PTO_413\						
Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date							
Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	5) Notice of Informal Pa 6) Other:	tent Application (PTO-152)						
		· · · · · · · · · · · · · · · · · · ·						

Application/Control Number: 09/937,306

Art Unit: 1654

#### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Page 3

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 4, 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/09653 (US 6,297,281 cited to shown English version of the document).

WO teaches the separated elements (N-acetylcysteine and aminoguanidine), see abstract of the 6297281 patent, also see col. 4, lines 38-51, col. 5, line53-col. 6, line 15, and the claims.

In response to the language "consisting essentially of" in the claim, applicant is reminded of MPEP 2111.03:

For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising," See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not

materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of language.").

Claims 1, 4, 8-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Naftchi et al. '933 or '962.

Applicant argues that the patents disclose a reaction product of two compounds. While this may be true, they still do start with the two compounds lipoic acid and aminoguanidine, see col. 133, under number 208, of Naftchi '933. In Naftchi '962 at col. 119, number 208, the same compounds are shown. All the claims require is the that the compounds are separate which they are before they are reacted.

In response to the language "consisting essentially of" in the claim, applicant is reminded of MPEP 2111.03:

For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional

Art Unit: 1654

steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Exparte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of language.").

#### Claim Rejections - 35 USC § 103

Claims 1, 4, 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naftchi et al. '933, Naftchi et al. '962, Petrus, Lai, or WO 98/09653 (US 6,297,281 cited to shown English version of the document).

The teachings and arguments of the Naftchi references are discussed above. Applicant argues that Petrus uses an aminosugar and therefore cannot teach the claimed invention because the claimed invention uses the language, "consisting essentially of". The composition can be administered in oral form, thus one could administer the composition in a glass of orange juice which would have vitamin C in it. Thus, Vitamin C in this instance is another ingredient which could read on "consisting essentially of".

Application/Control Number: 09/937,306

Art Unit: 1654

In response to the language "consisting essentially of" in the claim, applicant is reminded of MPEP 2111.03:

For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps... [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of language.").

Thus, the claimed invention is still obvious over the cited references.

As far as Lai is concerned, it does teach the use of lipoic acid on col. 12, line 62 and aminoguanidine, col. 21, line 45-55, which is of record. Both of these elements are first in separate form before being combined in one combined formulation.

As for the WO reference, comments concerning it are above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael V. Meller Primary Examiner Art Unit 1654

MVM

Application/Control Number: 09/937,306

Art Unit: 1654

Page 8